REMARKS/ARGUMENTS

Rejection of claims 1, 20-24, 28, and 29 under 35 U.S.C. 112, first paragraph, should be withdrawn.

The application on pages 11-14 sets forth in precise detail how to administer Rhodamine-123 in the treatment of patients with prostate cancer, one form of carcinoma. Clinical tests in accordance with that protocol showed a substantial decrease in Prostate-Specific Antigen (PSA) for 4 out of 12 patients. Moreover, for two of those patients the decrease in PSA exceeded 50%. This is important because Kantoff, P.W. et al. reported in the *Journal of Clinical Oncology*, Vol. 17 No. 8 (August, 1999): pp. 2506-2513, at page 2509 that median survival time for patients with hormone refractory prostate cancer is significantly extended if a patient has a 50% or greater drop in PSA level after treatment. See the February 23, 2001 declaration of Lawrence W. Jones, M.D., the Principal Investigator for the clinical tests.

Contrary to the assertion in the Office action, undue experimentation is not required to practice applicant's invention. The applicant's disclosure provides considerable direction and guidance on how to practice the invention, and presents working examples. As recognized in the Office action, there is a high level of skill in the art of cancer research, and all the steps needed to practice the invention are clear from applicant's disclosure. The Examiner can take judicial

notice that this was also true at the time the first application was filed in 1995.

Unfortunately, the nature of carcinoma is such that there is presently no way to predict with certainty that a specific type of treatment will be successful. Nevertheless, that does not require undue experimentation in practicing the invention. But it does require expensive and time-consuming clinical tests to demonstrate effective treatment. This is similar to the monoclonal antibody technology involved in the case of *In re Wands* 8 U.SP.Q. 2d 1400 (CAFC 1988) cited in the Office action, and which reversed the decision of the Board of Patent Appeals and Inteferences.

The applicant is first to show how to use Rhodamine-123 in treating patients with carcinoma, such as prostate cancer. The clinical tests demonstrating the efficacy of applicant's invention were expensive, and time-consuming. It would be unfair and unreasonable to limit the scope of applicant's claims because he did not have sufficient time and assets to demonstrate the efficacy of his treatment in clinical tests on a variety of carcinomas. His application presents a clear blueprint to other workers in the art how to practice his invention. Those skilled in the art would have no difficulty, given sufficient time, money and available patients, in using applicant's invention to treat patients with other types of carcinoma without any undue experimentation. For example, the clinical tests performed in accordance with applicant's protocol set forth in the application have demonstrated that Rhodamine-

123 can be administered in effective amounts without causing toxicity. Those skilled in the art would not have to experiment unduly to adjust the protocol as may be necessary to accommodate patients who might have tolerances different from those participating in the clinical tests described in the declarations of Dr. Jones, and which are of record in the prosecution of this application.

Claims 3-8, 10-13, 15-16, 18-19, 21-24, 26 and 28 have each been amended to change "A" to "The" to facilitate the prosecution of the application.

The objection to claims 3, 4, 10, 20, 26 and 27 because of the word "including" is not understood. The word in question makes it clear that the limitations following the word are part of the claimed invention. If this rejection is repeated, applicant requests an explanation how the word makes it unclear that the limitations following it are part of the claimed invention.

With reference, to the application at page 14, lines 9-11, which refer to the treatment solution, it is clear that the alcohol is ethyl alcohol. For example, see page 13, lines 11-12 which state "the treatment solution will include between about 0.2% and about 5% ethyl alcohol by volume."

Claims 1-30 are patentable over Bernal or Arcadi (J. Surg. Onc. 1990), even in view of U.S. Pat. No. 5,880,141 to Tang et al, EMBASE 94148842, or MEDLINE AN 93172422, because the combination of references enters the "tempting but forbidden

zone of hindsight" condemned by the U.S. Court of Appeals for the Federal Circuit in reversing the Board of Patent Appeals and Interferences in the case of *In re Dembiczak*, 50 U.S.P.Q. 2d 1614, at p. 1616. As stated by the *Dembiczak* Court, "Measuring a claimed invention against the standard established by Section 103 requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field." (at page 1617) The Court further stated that:

> "the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references."

* * *

"Combining prior art references without evidence of such a suggestion, teaching or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability — the essence of hindsight." (at page 1617)

As the *Dembiczak* Court stated (at page 1617) "the Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select the

references and combine them". The Office action does not identify any reason for such combination.

There is no teaching or motivation in either the primary or secondary cited reference for combining them to achieve applicant's invention, and the Office does not identify any reason for such combination.

In view of the controlling case law, the rejection of claims 1-30 should be withdrawn.

Respectfully submitted,
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